

FAQS: CLINICAL TRIALS FOR COVID-19 TREATMENTS

THE BASICS

Q: What is a clinical trial?

Clinical trials are research studies that help scientists discover better ways to prevent, treat, or cure disease. To make these discoveries work for all of us, people from every community are needed to participate in clinical trials.

Q: Why do we need to research new treatments when we have vaccines for COVID-19?

A vaccine is used to prevent people from getting a disease; treatments are used to help people who are already sick recover from the disease. We need new treatments for people who are sick with COVID-19, or who can't take the vaccine due to another medical condition.

Q: Aren't monoclonal antibodies an effective treatment for COVID-19? Why do we need to test other treatments?

Monoclonal antibodies (mAbs) are authorized for emergency use by the U.S. Food and Drug Administration (FDA) to treat people who have had mild or moderate symptoms of COVID-19 for 10 days or less, and who are at high risk for more serious symptoms. mAbs can reduce the risk of getting more serious symptoms of COVID-19 or needing to be hospitalized. But not everyone is a good candidate for mAbs. Some people are too sick; some people who have been exposed to COVID-19 barely have symptoms, or even have no symptoms.

The more effective and safe treatments for COVID-19 we have for people at different stages of COVID-19, the sooner we'll get back to normal.

Q: Why should I consider participating in a clinical trial for COVID-19 treatments?

Participating in a clinical trial is one of the most important ways you can help to end COVID-19. The fact is, while COVID-19 has impacted everybody, it's hit the Black and Hispanic/Latino populations especially hard. This is largely due to social and economic factors that affect some communities more than others. Also, treatments' effectiveness can vary by race and ethnicity. When people of all races and ethnicities participate in clinical trials, researchers can discover preventions and treatments that work for everybody.

Q: How could I benefit from participating?

You may get access to a new treatment only available to participants. During the clinical trial, you'll receive healthcare that's focused on your specific needs. You also may be paid for your time. Best of all, you'll have taken action to protect yourself and your loved ones—now and in the future.

THE PROCESS

Q: What happens in a clinical trial?

You get the best healthcare available. Treatments are offered in what the FDA calls the "gold standard" for research studies: a "randomized, double-blind, placebo-controlled clinical trial. In these trials, there are two groups of participants. Some participants are assigned randomly to the group that receives the drug being tested, and some are assigned randomly to a "control" group that receives a placebo. (A placebo looks like the drug being tested but it actually has none of the active drug in it.) But it's important to know that everyone who participates in a clinical trial for COVID-19 treatment receives a treatment for COVID-19. Participants who don't receive the drug being tested receive another treatment for the disease.

Q: Is it safe for me to participate in a clinical trial?

There are strict laws that require clinical trials to guard both your safety and your privacy. Every clinical trial must be carefully reviewed in advance by a group of scientists as well as an **Institutional Review Board** who work to make sure the clinical trial is safe and that it protects your rights.

Before you join a clinical trial, ask your research team any questions you may have. This is part of the **informed consent** process, where the researchers will explain to you the goals of the clinical trial, all the possible risks and benefits of participating, how long the study will take, and much more.

Q: If I decide to participate, can I drop out of the clinical trial before it ends?

Yes. You can leave a clinical trial at any time. A medical team will continue to check on you—even if you drop out before the study ends—to make sure you don't experience any negative effects as a result of the trial.

Q: Is my participation in a clinical trial covered by my insurance?

Clinical trials and the treatments given are offered to you at no cost.

Q: If I participate, will I have to show my immigration status?

No. Your privacy is protected by a federal law known as HIPAA (the **Health Insurance Portability and Accountability Act**). Your name remains secret and is not mentioned in any reports or shared with any government agency. Ever.

GETTING STARTED

Q: Do I need a referral or permission from a healthcare provider to join a clinical trial?

No, you do not need a referral. But you may want to discuss the benefits of joining a clinical trial with your healthcare provider just to be sure it's the right choice for you.

Q: How do I know if I can participate in a COVID-19 clinical trial for treatments?

Clinical trials are going on right now. You may be eligible to join one if you:

- Have been exposed to COVID-19, but have not developed symptoms
- Have symptoms of COVID-19, but have not been hospitalized
- Are hospitalized now due to COVID-19
- Were hospitalized due to COVID-19 and have been discharged from the hospital

Q: Where can I learn more?

Visit <https://CombatCOVID.hhs.gov/Clinical-Trials> or call 877-414-8106 to speak with an information specialist who can answer your questions.

Q: I speak Spanish, not English. Can I still participate in a clinical trial?

Yes! The website <https://CombateCOVID.hhs.gov> has information in Spanish as well as a toll-free number. Call 877-414-8106 to speak with an information specialist who can answer your questions in Spanish.